Claims

1. A method for treating a condition characterized by abnormal mammalian cell proliferation comprising

administering to a subject in need thereof an agent of Formula I in an effective amount to inhibit the condition,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

2. The method of claim 1, wherein the condition is a cancer.

3. The method of claim 1, wherein the condition is a premalignant condition.

4. The method of claim 1, wherein the condition is a benign tumor.

5. The method of claim 1, wherein the abnormal cell proliferation is abnormal angiogenesis.

6. The method of claim 1, further comprising administering to the subject an anti-cancer therapy other than an agent of Formula I.

7. The method of claim 6, wherein the anti-cancer therapy is surgery, radiation or chemotherapy.

8. The method of claim 7, wherein chemotherapy is selected from the group consisting of aldesleukin, asparaginase, bleomycin sulfate, carboplatin, chlorambucil, cisplatin, cladribine, cyclophosphamide, cytarabine, dacarbazine, dactinomycin, daunorubicin hydrochloride, docetaxel, doxorubicin, doxorubicin hydrochloride, epirubicin hydrochloride, etoposide, etoposide phosphate, floxuridine, fludarabine, fluorouracil, gemcitabine, gemcitabine hydrochloride, hydroxyurea, idarubicin hydrochloride, ifosfamide, interferons, interferon-α2a, interferon-α2b, interferon-αn3, interferon-α1b, interleukins, irinotecan, mechlorethamine hydrochloride, melphalan, mercatopurine, methotrexate, methotrexate sodium, mitomycin, mitoxantrone, paclitaxel, pegaspargase, pentostatin, prednisone, profimer sodium, procabazine hydrochloride, taxol, taxotere, teniposide, topotecan hydrochloride, vinblastine sulfate, vincristine sulfate or vinorelbine tartrate.

9. The method of claim 6, wherein the agent of Formula I is administered prior to or after the anti-cancer therapy.

10. The method of claim 6, wherein the agent of Formula I is administered substantially simultaneously with the anti-cancer therapy.

11. The method of claim 7, wherein the agent of Formula I is administered daily and the chemotherapy is administered weekly, biweekly, or every three weeks.

12. The method of claim 1, wherein the agent of Formula I is administered twice a day.

13. A method for treating an infectious disease comprising

administering to a subject in need thereof an agent of Formula I in an effective amount to inhibit the infectious disease,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

14. The method of claim 13, further comprising administering to the subject an anti-microbial agent.

15. The method of claim 14, wherein the anti-microbial agent is an anti-bacterial agent, an anti-viral agent, an anti-fungal agent, an anti-parasitic agent or an anti-mycobacterial agent.

16. The method of claim 15, wherein the anti-microbial agent is an anti-bacterial agent.

17. The method of claim 16, wherein the anti-bacterial agent is an antibiotic.

18. The method of claim 17, wherein the antibiotic is a broad spectrum antibiotic, a narrow spectrum antibiotic, or a limited spectrum antibiotic.

19. The method of claim 16, wherein the anti-bacterial agent is selected from the group consisting of cell wall synthesis inhibitor, cell membrane inhibitor, protein synthesis inhibitor, nucleic acid synthesis or functional inhibitor and competitive inhibitor.

20. The method of claim 16, wherein the anti-bacterial agent is selected from the group consisting of natural penicillins, semi-synthetic penicillins, clavulanic acid, cephalolsporins, bacitracin, ampicillin, carbenicillin, oxacillin, azlocillin, mezlocillin, piperacillin, methicillin, dicloxacillin, nafcillin, cephalothin, cephapirin, cephalexin, cefamandole, cefaclor, cefazolin, cefuroxine, cefoxitin, cefotaxime, cefsulodin, cefetamet, cefixime, ceftriaxone, cefoperazone, ceftazidine, moxalactam, carbapenems, imipenems, monobactems, euztreonam, vancomycin, polymyxin, amphotericin B, nystatin, imidazoles, clotrimazole, miconazole, ketoconazole, itraconazole, fluconazole, rifampins, ethambutol, tetracyclines, chloramphenicol, macrolides, aminoglycosides, streptomycin, kanamycin, tobramycin, amikacin, gentamicin, tetracycline, minocycline, doxycycline, chlortetracycline, erythromycin, roxithromycin, clarithromycin, oleandomycin, azithromycin, chloramphenicol, quinolones, co-trimoxazole, norfloxacin, ciprofloxacin, enoxacin, nalidixic acid, temafloxacin, sulfonamides, gantrisin, and trimethoprim.

21. The method of claim 16, wherein the anti-bacterial agent is selected from the group consisting of acedapsone; acetosulfone sodium; alamecin; alexidine; amdinocillin; amdinocillin pivoxil; amicycline; amifloxacin; amifloxacin mesylate; amikacin; amikacin sulfate; aminosalicylic acid; aminosalicylate sodium; amoxicillin; amphomycin; ampicillin; ampicillin sodium; apalcillin sodium; apramycin; aspartocin; astromicin sulfate; avilamycin; avoparcin; azithromycin; azlocillin; azlocillin sodium; bacampicillin hydrochloride; bacitracin; bacitracin methylene disalicylate; bacitracin zinc; bambermycins; benzoylpas calcium; berythromycin ; betamicin sulfate; biapenem; biniramycin; biphenamine hydrochloride ; bispyrithione magsulfex ; butikacin; butirosin sulfate; capreomycin sulfate; carbadox; carbenicillin disodium; carbenicillin indanyl sodium; carbenicillin phenyl sodium; carbenicillin potassium; carumonam sodium; cefaclor; cefadroxil; cefamandole; cefamandole nafate; cefamandole sodium; cefaparole; cefatrizine; cefazaflur sodium; cefazolin; cefazolin sodium; cefbuperazone; cefdinir; cefepime; cefepime hydrochloride; cefetecol; cefixime; cefmenoxime hydrochloride; cefmetazole; cefmetazole sodium; cefonicid monosodium; cefonicid sodium; cefoperazone sodium; ceforanide; cefotaxime sodium; cefotetan; cefotetan disodium; cefotiam hydrochloride; cefoxitin; cefoxitin sodium; cefpimizole; cefpimizole sodium; cefpiramide; cefpiramide sodium; cefpirome sulfate; cefpodoxime proxetil; cefprozil; cefroxadine; cefsulodin sodium; ceftazidime; ceftibuten; ceftizoxime sodium; ceftriaxone sodium; cefuroxime; cefuroxime axetil; cefuroxime pivoxetil; cefuroxime sodium; cephacetrile sodium; cephalexin; cephalexin hydrochloride; cephaloglycin; cephaloridine; cephalothin sodium; cephapirin sodium; cephradine; cetocycline hydrochloride; cetophenicol; chloramphenicol ; chloramphenicol palmitate ; chloramphenicol pantothenate complex ; chloramphenicol sodium succinate;

chlorhexidine phosphanilate; chloroxylenol; chlortetracycline bisulfate ; chlortetracycline hydrochloride ; cinoxacin; ciprofloxacin; ciprofloxacin hydrochloride; cirolemycin ; clarithromycin; clinafloxacin hydrochloride; clindamycin; clindamycin hydrochloride; clindamycin palmitate hydrochloride; clindamycin phosphate; clofazimine ; cloxacillin benzathine; cloxacillin sodium; cloxyquin; colistimethate sodium; colistin sulfate; coumermycin; coumermycin sodium; cyclacillin; cycloserine; dalfopristin; dapsone ; daptomycin; demeclocycline; demeclocycline hydrochloride; demecycline; denofungin ; diaveridine; dicloxacillin; dicloxacillin sodium; dihydrostreptomycin sulfate; dipyrithione; dirithromycin; doxycycline; doxycycline calcium ; doxycycline fosfatex; doxycycline hyclate; droxacin sodium; enoxacin; epicillin; epitetracycline hydrochloride; erythromycin; erythromycin acistrate; erythromycin estolate; erythromycin ethylsuccinate; erythromycin gluceptate; erythromycin lactobionate; erythromycin propionate; erythromycin stearate; ethambutol hydrochloride; ethionamide; fleroxacin; floxacillin; fludalanine; flumequine; fosfomycin; fosfomycin tromethamine; fumoxicillin; furazolium chloride; furazolium tartrate; fusidate sodium; fusidic acid; gentamicin sulfate; gloximonam; gramicidin; haloprogin; hetacillin; hetacillin potassium; hexedine; ibafloxacin; imipenem; isoconazole; isepamicin; isoniazid; josamycin; kanamycin sulfate; kitasamycin; levofuraltadone; levopropylcillin potassium; lexithromycin; lincomycin; lincomycin hydrochloride; lomefloxacin; lomefloxacin hydrochloride; lomefloxacin mesylate; loracarbef; mafenide; meclocycline; meclocycline sulfosalicylate; megalomicin potassium phosphate; mequidox; meropenem; methacycline; methacycline hydrochloride; methenamine; methenamine hippurate; methenamine mandelate; methicillin sodium; metioprim; metronidazole hydrochloride; metronidazole phosphate; mezlocillin; mezlocillin sodium; minocycline; minocycline hydrochloride; mirincamycin hydrochloride ; monensin ; monensin sodium ; nafcillin sodium; nalidixate sodium; nalidixic acid; natamycin; nebramycin; neomycin palmitate; neomycin sulfate; neomycin undecylenate ; netilmicin sulfate; neutramycin; nifuradene; nifuraldezone; nifuratel ; nifuratrone; nifurdazil; nifurimide; nifurpirinol; nifurquinazol; nifurthiazole; nitrocycline; nitrofurantoin; nitromide; norfloxacin; novobiocin sodium; ofloxacin; ormetoprim; oxacillin sodium; oximonam; oximonam sodium; oxolinic acid; oxytetracycline; oxytetracycline calcium; oxytetracycline hydrochloride; paldimycin; parachlorophenol; paulomycin; pefloxacin; pefloxacin mesylate; penamecillin; penicillin g benzathine; penicillin g potassium; penicillin g procaine; penicillin g sodium; penicillin v; penicillin v benzathine; penicillin v hydrabamine; penicillin v potassium; pentizidone sodium; phenyl aminosalicylate; piperacillin sodium; pirbenicillin sodium; piridicillin sodium; pirlimycin hydrochloride; pivampicillin hydrochloride; pivampicillin pamoate; pivampicillin probenate; polymyxin b sulfate; porfiromycin ; propikacin; pyrazinamide; pyrithione zinc; quindecamine acetate; quinupristin; racephenicol; ramoplanin; ranimycin; relomycin; repromicin; rifabutin; rifametane; rifamexil; rifamide; rifampin; rifapentine; rifaximin;

rolitetracycline; rolitetracycline nitrate; rosaramicin; rosaramicin butyrate; rosaramicin propionate; rosaramicin sodium phosphate; rosaramicin stearate; rosoxacin; roxarsone; roxithromycin; sancycline; sanfetrinem sodium; sarmoxicillin; sarpicillin; scopafungin ; sisomicin; sisomicin sulfate; sparfloxacin; spectinomycin hydrochloride; spiramycin; stallimycin hydrochloride; steffimycin; streptomycin sulfate; streptonicozid; sulfabenz ; sulfabenzamide; sulfacetamide; sulfacetamide sodium; sulfacytine; sulfadiazine; sulfadiazine sodium; sulfadoxine; sulfalene; sulfamerazine; sulfameter; sulfamethazine; sulfamethizole; sulfamethoxazole; sulfamonomethoxine; sulfamoxole; sulfanilate zinc; sulfanitran ; sulfasalazine; sulfasomizole; sulfathiazole; sulfazamet; sulfisoxazole; sulfisoxazole acetyl; sulfisoxazole diolamine; sulfomyxin; sulopenem; sultamicillin; suncillin sodium; talampicillin hydrochloride; teicoplanin; temafloxacin hydrochloride; temocillin; tetracycline; tetracycline hydrochloride; tetracycline phosphate complex; tetroxoprim; thiamphenicol; thiphencillin potassium; ticarcillin cresyl sodium; ticarcillin disodium; ticarcillin monosodium; ticlatone; tiodonium chloride; tobramycin; tobramycin sulfate; tosufloxacin; trimethoprim; trimethoprim sulfate; trisulfapyrimidines; troleandomycin; trospectomycin sulfate; tyrothricin; vancomycin; vancomycin hydrochloride; virginiamycin; and zorbamycin.

22. The method of claim 15, wherein the anti-microbial agent is an anti-viral agent.

23. The method of claim 22, wherein the anti-viral agent is selected from the group consisting of immunoglobulin, amantadine, interferon, nucleoside analogue, nonnucleoside analogue, biflavanoid and protease inhibitor.

24. The method of claim 23, wherein the protease inhibitor is indinavir, saquinavir, ritonavir, and nelfinavir.

25. The method of claim 23, wherein the biflavanoid is robustaflavone, amentoflavone, or a derivative or salt thereof.

26. The method of claim 22, wherein the antiviral agent is selected from the group consisting of AZT, ddC, ddI, D4T, 3TC, acemannan; acyclovir; acyclovir sodium; adefovir; alovudine; alvircept sudotox; amantadine hydrochloride; aranotin; arildone; atevirdine mesylate; avridine; cidofovir; cipamfylline; cytarabine hydrochloride; delavirdine mesylate; desciclovir; didanosine; disoxaril; edoxudine; enviradene; enviroxime; famciclovir; famotine hydrochloride; fiacitabine; fialuridine;

fluorinated nucleosides; fosarilate; foscarnet sodium; fosfonet sodium; ganciclovir; ganciclovir sodium; idoxuridine; kethoxal; lamivudine; lobucavir; memotine hydrochloride; methisazone; nevirapine; penciclovir; pirodavir; ribavirin; rimantadine hydrochloride; saquinavir mesylate; somantadine hydrochloride; sorivudine; statolon; stavudine; tilorone hydrochloride; trifluridine; valacyclovir hydrochloride; vidarabine; vidarabine phosphate; vidarabine sodium phosphate; viroxime; zalcitabine; zidovudine; and zinviroxime.

27. The method of claim 23, wherein the non-nucleoside analogue is selected from the group consisting of delavirdine, nevirapine, efavirenz, alpha-interferon, recombinant CD4, amantadine, rimantadine, ribavirin and vidarabine.

28. The method of claim 15, wherein the anti-microbial agent is an anti-fungal agent.

29. The method of claim 28, wherein the anti-fungal agent is selected from the group consisting of imidazole, FK 463, amphotericin B, BAY 38-9502, MK 991, pradimicin, UK 292, butenafine, chitinase and 501 cream.

30. The method of claim 28, wherein the anti-fungal agent is selected from the group consisting of acrisorcin; ambruticin; amorolfine, amphotericin b; azaconazole; azaserine; basifungin; bifonazole; biphenamine hydrochloride ; bispyrithione magsulfex ; butoconazole nitrate; calcium undecylenate; candicidin; carbol-fuchsin; chlordantoin; ciclopirox; ciclopirox olamine; cilofungin; cisconazole; clotrimazole; cuprimyxin ; denofungin ; dipyrithione; doconazole; econazole; econazole nitrate; enilconazole; ethonam nitrate; fenticonazole nitrate; filipin; fluconazole; flucytosine; fungimycin; griseofulvin; hamycin; isoconazole ; itraconazole; kalafungin; ketoconazole; lomofungin; lydimycin; mepartricin ; miconazole; miconazole nitrate; monensin ; monensin sodium ; naftifine hydrochloride; neomycin undecylenate ; nifuratel ; nifurmerone; nitralamine hydrochloride; nystatin; octanoic acid; orconazole nitrate; oxiconazole nitrate; oxifungin hydrochloride; parconazole hydrochloride; partricin ; potassium iodide ; proclonol ; pyrithione zinc ; pyrrolnitrin; rutamycin; sanguinarium chloride ; saperconazole; scopafungin ; selenium sulfide ; sinefungin; sulconazole nitrate; terbinafine; terconazole; thiram; ticlatone ; tioconazole; tolciclate; tolindate; tolnaftate; triacetin; triafungin; undecylenic acid; viridofulvin; zinc undecylenate; and zinoconazole hydrochloride.

31. The method of claim 28, wherein the anti-microbial agent is an anti-parasitic agent.

32. The method of claim 15, wherein the anti-parasitic agent is selected from the group consisting of albendazole, amphotericin B, benznidazole, bithionol, chloroquine HCl, chloroquine phosphate, clindamycin, dehydroemetine, diethylcarbamazine, diloxanide furoate, eflornithine, furazolidaone, glucocorticoids, halofantrine, iodoquinol, ivermectin, mebendazole, mefloquine, meglumine antimoniate, melarsoprol, metrifonate, metronidazole, niclosamide, nifurtimox, oxamniquine, paromomycin, pentamidine isethionate, piperazine, praziquantel, primaquine phosphate, proguanil, pyrantel pamoate, pyrimethanmine-sulfonamides, pyrimethanmine-sulfadoxine, quinacrine HCl, quinine sulfate, quinidine gluconate, spiramycin, stibogluconate sodium (sodium antimony gluconate), suramin, tetracycline, doxycycline, thiabendazole, tinidazole, trimethroprim-sulfamethoxazole, and tryparsamide.

33. The method of claim 15, wherein the anti-microbial agent is an anti-mycobacterial agent.

34. The method of claim 33, wherein the anti-mycobacterial agent is an anti-tuberculosis agent.

35. The method of claim 34, wherein the anti-tuberculosis agent is isoniazid, rifampin, rifabutin, rifapentine, pyrazinamide, ethambutol, (+)calanolide A, (-)-calanolide A, (-)-soulattrolide, (-)-costatolide or (-)-7,8-dihydrosoulattrolide

36. The method of claim 33, wherein the anti-mycobacterial agent is streptomycin, dapsone, clarithromycin, ciprofloxacin, clofazamine, azithromycin, ethionamide, amikacin or resorcinomycin A.

37. The method of claim 14, wherein the agent of Formula I is administered prior to or after the anti-microbial agent.

38. The method of claim 14, wherein the agent of Formula I is administered substantially simultaneously with the anti-microbial agent.

39. The method of claim 1 or 13, wherein the agent of Formula I is provided as a pharmaceutical preparation prepared within thirty minutes of administration.

40. A pharmaceutical preparation comprising

an agent of Formula I in a dosage of about 0.005 mg/kg to less than 1.0 mg/kg per day, and

a pharmaceutically acceptable carrier,

wherein the preparation is formulated for injection or in an enterically coated form.

41. The pharmaceutical preparation of claim 40, wherein the preparation is provided in a vial or ampoule with a septum.

42. A kit comprising

a housing and

the pharmaceutical preparation of claim 40.

43. The kit of claim 42, further comprising instructions for use.

44. A pharmaceutical preparation comprising

an agent of Formula I in a dosage of less than 1.0 mg/kg per day,

wherein the preparation is provided in a vial or ampoule with a septum.

45. The pharmaceutical preparation of claim 40 or 44, wherein the dosage is about 0.005 to less than or equal to 0.1 mg/kg per day.

46. The pharmaceutical preparation of claim 40 or 44, wherein the preparation is sterile and pyrogen-free.

47. The pharmaceutical preparation of claim 44, further comprising a pharmaceutically acceptable carrier.

48. The pharmaceutical preparation of claim 40 or 47, wherein the pharmaceutically acceptable carrier comprises a solubilizer, an anti-bacterial preservative, an anti-oxidant or a pharmaceutical adjunct.

49. The pharmaceutical preparation of claim 48, wherein the anti-oxidant is sodium bisulfite.

50. The pharmaceutical preparation of claim 40 or 44, wherein the preparation comprises distilled water or reverse-osmosis water.

51. The pharmaceutical preparation of claim 50, wherein the anti-bacterial preservative is phenylmercuric nitrate, thimerosal, benzetheonium chloride, benzalkonium chloride, phenol, cresol or chlorobutanol.

52. The pharmaceutical preparation of claim 40 or 47, wherein the pharmaceutically acceptable carrier has a pH of less than 5.

53. The pharmaceutical preparation of claim 40 or 47, wherein the pharmaceutically acceptable carrier has a pH of between 2.0 and 5.0.

54. The pharmaceutical preparation of claim 40 or 47, wherein the pharmaceutically acceptable carrier has a pH of between 3.0 and 5.0.

55. The pharmaceutical preparation of claim 40 or 47, wherein the pharmaceutically acceptable carrier has a pH of between 3.0 and 4.5.

56. The pharmaceutical preparation of claim 40 or 47, wherein the pharmaceutically acceptable carrier has a pH of between 3.0 and 4.25.

57. The pharmaceutical preparation of claim 40 or 47, wherein the pharmaceutically acceptable carrier has a pH of between 3.0 and 4.0.

58. The pharmaceutical preparation of claim 40 or 47, wherein the pharmaceutically acceptable carrier has a pH of between 3.0 and 3.5.

59. A method of producing the pharmaceutical preparation of claim 44, comprising combining the agent of Formula I with a pharmaceutically acceptable carrier.

60. The method of claim 59, wherein the combining occurs within 30 minutes of administration to a subject.

61. A kit comprising
a housing that comprises
an agent of Formula I in a first container, and
a pharmaceutically acceptable carrier in a second container,
wherein the agent of Formula I is present in a dried form.

62. The kit of claim 61, wherein the agent and carrier are sterile and pyrogen-free.

63. The kit of claim 61, wherein the pharmaceutically acceptable carrier comprises a solubilizer, an anti-bacterial preservative, an anti-oxidant or a pharmaceutical adjunct.

64. The kit of claim 63, wherein the anti-oxidant is sodium bisulfite.

65. The kit of claim 61, wherein the carrier comprises distilled water or reverse-osmosis water.

66. The kit of claim 63, wherein the anti-bacterial preservative is phenylmercuric nitrate, thimerosal, benzetheonium chloride, benzalkonium chloride, phenol, cresol or chlorobutanol.

67. The kit of claim 61, wherein the pharmaceutically acceptable carrier has a pH of less than 5.

68. The kit of claim 61, wherein the pharmaceutically acceptable carrier has a pH of between 2.0 and 5.0.

69. The kit of claim 61, wherein the pharmaceutically acceptable carrier has a pH of between 3.0 and 5.0.

70. The kit of claim 61, wherein the pharmaceutically acceptable carrier has a pH of between 3.0 and 4.5.

71. The kit of claim 61, wherein the pharmaceutically acceptable carrier has a pH of between 3.0 and 4.25.

72. The kit of claim 61, wherein the pharmaceutically acceptable carrier has a pH of between 3.0 and 4.0.

73. The kit of claim 61, wherein the pharmaceutically acceptable carrier has a pH of between 3.0 and 3.5.

74. The kit of claim 61, wherein the kit comprises a plurality of first and second containers corresponding to a number of administrations to a subject.

75. The kit of claim 61, wherein the first container is a vial or ampoule with a septum.

76. The kit of claim 61 or 75, wherein the second container is a vial or ampoule with a septum.

77. A kit comprising

a housing that comprises

an agent of Formula I dissolved in an acid solution in a first container, and

a neutral or basic isotonic diluent in a second container.

78. The kit of claim 61 or 77, further comprising instructions for administering the agent to a subject in need thereof.

79. The kit of claim 77, wherein the agent, solution and diluent are sterile and pyrogen-free.

80. The kit of claim 77, wherein the acid solution has a pH of less than 5.

81. The kit of claim 77, wherein the acid solution has a pH of between 2.0 and 5.0.

82. The kit of claim 77, wherein the acid solution has a pH of between 3.0 and 5.0.

83. The kit of claim 77, wherein the acid solution has a pH of between 3.0 and 4.5.

84. The kit of claim 77, wherein the acid solution has a pH of between 3.0 and 4.25.

85. The kit of claim 77, wherein the acid solution has a pH of between 3.0 and 4.0.

86. The kit of claim 77, wherein the acid solution has a pH of between 3.0 and 3.5.

87. The kit of claim 77, wherein the diluent has a pH greater than 5.

88. The kit of claim 77, wherein the diluent has a pH of between 5.0 and 8.0.

89. The kit of claim 77, wherein the diluent has a pH of between 5.0 and 7.5.

90. The kit of claim 77, wherein the diluent has a pH of between 5.0 and 7.0.

91. The kit of claim 77, wherein the diluent has a pH of between 5.0 and 6.5.

92. The kit of claim 77, wherein the diluent has a pH of between 5.0 and 6.0.

93. The kit of claim 77, wherein the diluent has a pH of between 5.0 and 5.5.

94. A kit comprising

an agent of Formula I in a first container, and

instructions for diluting the agent in a neutral or acidic injectable diluent.

95. The kit of claim 94, further comprising a housing comprising the first container and the instructions.

96. The kit of claim 61, 77 or 94, wherein the agent is formulated in a dosage of about 0.005 mg/kg to less than 1.0 mg/kg per day.

97. The kit of claim 61, 77 or 94, wherein the agent is formulated in a dosage of about 0.005 mg/kg to less than or equal to 0.1 mg/kg per day.

98. The kit of claim 94, wherein the agent is sterile and pyrogen-free.

99. The kit of claim 77 or 94, wherein the diluent comprises a solubilizer, an anti-bacterial preservative, an anti-oxidant or a pharmaceutical adjunct.

100. The kit of claim 99, wherein the anti-oxidant is sodium bisulfite.

101. The kit of claim 77 or 94, wherein the diluent comprises distilled water or reverse-osmosis water.

102. The kit of claim 99, wherein the anti-bacterial preservative is phenylmercuric nitrate, thimerosal, benzetheonium chloride, benzalkonium chloride, phenol, cresol or chlorobutanol.

103. The kit of claim 94, wherein the diluent has a pH of less than 7.

104. The kit of claim 94, wherein the diluent has a pH of between 2.0 and 7.0.

105. The kit of claim 94, wherein the diluent has a pH of between 3.0 and 6.0.

106. The kit of claim 94, wherein the diluent has a pH of between 3.0 and 5.0.

107. The kit of claim 94, wherein the diluent has a pH of between 3.0 and 4.25.

108. The kit of claim 94, wherein the diluent has a pH of between 3.0 and 4.0.

109. The kit of claim 94, wherein the diluent has a pH of between 3.0 and 3.5.

110. The kit of claim 61, 77 or 94, wherein the kit comprises a plurality of first containers corresponding to a number of administrations to a subject.

111. The kit of claim 94, wherein the first container is a vial or ampoule with a septum.

112. A method for stimulating an immune response in a subject comprising administering to a subject in need of immune stimulation an agent of Formula I, and an antibody or antibody fragment, in an amount effective to stimulate an immune response,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

113. The method of claim 112, wherein the immune response is antibody dependent cell-mediated cytoxicity.

114. The method of claim 112, wherein the antibody or antibody fragment is an antibody.

115. The method of claim 112, wherein the antibody or antibody fragment is selected from the group consisting of trastuzumab, alemtuzumab (B cell chronic lymphocytic leukemia), gemtuzumab ozogamicin (CD33+ acute myeloid leukemia), hP67.6 (CD33+ acute myeloid leukemia), infliximab (inflammatory bowel disease and rheumatoid arthritis), etanercept (rheumatoid arthritis), rituximab, tositumomab, MDX-210, oregovomab, anti-EGF receptor mAb, MDX-447, anti-tissue factor protein (TF), (Sunol); ior-c5, c5, edrecolomab, ibritumomab tiuxetan, anti-idiotypic mAb mimic of ganglioside GD3 epitope, anti-HLA-Dr10 mAb, anti-CD33 humanized mAb, anti-CD52 humAb, anti-CD1 mAb (ior t6), MDX-22, celogovab, anti-17-1A mAb, bevacizumab, daclizumab, anti-TAG-72 (MDX-220), anti-idiotypic mAb mimic of high molecular weight proteoglycan (I-Mel-1), anti-idiotypic mAb mimic of high molecular weight proteoglycan (I-Mel-2), anti-CEA Ab, hmAbH11, anti-DNA or DNA-associated proteins (histones) mAb, Gliomab-H mAb, GNI-250 mAb, anti-CD22, CMA 676), anti-idiotypic human mAb to GD2 ganglioside, ior egf/r3, anti-ior c2 glycoprotein mAb, ior c5, anti-FLK-2/FLT-3 mAb, anti-GD-2 bispecific mAb, antinuclear autoantibodies, anti-HLA-DR Ab, anti-CEA mAb, palivizumab, bevacizumab, alemtuzumab, BLyS-mAb, anti-VEGF2, anti-Trail receptor; B3 mAb, mAb BR96, breast cancer; and Abx-Cbl mAb.

116. The method of claim 112, wherein the antibody or antibody fragment is an anti-HER2 antibody.

117. The method of claim 116, wherein the anti-HER2 antibody is trastuzumab.

118. The method of claim 112, wherein the antibody or antibody fragment is an anti-CD20 antibody.

119. The method of claim 118, wherein the anti-CD20 antibody is rituximab.

120. The method of claim 112, wherein the antibody or antibody fragment is administered in a sub-therapeutic dose.

121. The method of claim 112, wherein the agent of Formula I is administered in a route of administration different from that of the antibody or antibody fragment.

122. The method of claim 112, wherein the agent of Formula I is administered prior to the antibody or antibody fragment.

123. The method of claim 122, wherein the agent of Formula I is administered 30 minutes to 8 hours prior to the antibody or antibody fragment.

124. The method of claim 122, wherein the agent of Formula I is administered 1 to 7 days prior to the antibody or antibody fragment.

125. The method of claim 112, wherein the agent of Formula I is administered substantially simultaneously with the antibody or antibody fragment.

126. The method of claim 112, wherein the agent of Formula I is administered after the antibody or antibody fragment.

127. The method of claim 126, wherein the agent of Formula I is administered 30 minutes to 8 hours after the antibody or antibody fragment.

128. The method of claim 126, wherein the agent of Formula I is administered 1 to 7 days after the antibody or antibody fragment.

129. A method for stimulating an immune response in a subject comprising

administering to a subject in need of immune stimulation an agent of Formula I, and an antigen, in an amount effective to stimulate an antigen-specific immune response,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

130. The method of claim 112 or 129, wherein the subject in need of immune stimulation is a subject having or at risk of developing cancer.

131. The method of claim 130, wherein the cancer is selected from the group consisting of basal cell carcinoma, biliary tract cancer; bladder cancer; bone cancer; brain cancer; breast cancer; cervical cancer; choriocarcinoma; CNS cancer; colon and rectum cancer; connective tissue cancer; cancer of the digestive system; endometrial cancer; esophageal cancer; eye cancer; cancer of the head and neck; gastric cancer; intra-epithelial neoplasm; kidney cancer; larynx cancer; leukemia; acute myeloid leukemia, acute lymphoid leukemia, chronic myeloid leukemia, chronic lymphoid leukemia, liver cancer; small cell lung cancer; non-small cell lung cancer; lymphoma, Hodgkin's lymphoma; Non-Hodgkin's lymphoma; melanoma; myeloma; neuroblastoma; oral cavity cancer; ovarian cancer; pancreatic cancer; prostate cancer; retinoblastoma; rhabdomyosarcoma; rectal cancer; renal cancer; cancer of the respiratory system; sarcoma; skin cancer; stomach cancer; testicular cancer; thyroid cancer; uterine cancer; and cancer of the urinary system.

132. The method of claim 170, wherein the cancer is a metastasis.

133. The method of claim 112 or 129, wherein the subject in need of immune stimulation is a subject having or at risk of developing an infectious disease.

134. The method of claim 133, wherein the infectious disease is selected from the group consisting of a bacterial infection, a mycobacterial infection, a viral infection, a fungal infection and a parasitic infection.

135. The method of claim 134, wherein the bacterial infection is selected from the group consisting of an E. coli infection, a Staphylococcal infection, a Streptococcal infection, a Pseudomonas infection, Clostridium difficile infection, Legionella infection, Pneumococcus infection, Haemophilus infection, Klebsiella infection, Enterobacter infection, Citrobacter infection, Neisseria infection, Shigella infection, Salmonella infection, Listeria infection, Pasteurella infection, Streptobacillus infection,

Spirillum infection, Treponema infection, Actinomyces infection, Borrelia infection, Corynebacterium infection, Nocardia infection, Gardnerella infection, Campylobacter infection, Spirochaeta infection, Proteus infection, Bacteriodes infection, H. pylori infection, and anthrax infection.

136. The method of claim 134, wherein the mycobacterial infection is selected from the group consisting of tuberculosis and leprosy.

137. The method of claim 134, wherein the viral infection is selected from the group consisting of an HIV infection, a Herpes simplex virus 1 infection, a Herpes simplex virus 2 infection, cytomegalovirus infection, hepatitis A virus infection, hepatitis B virus infection, hepatitis C virus infection, human papilloma virus infection, Epstein Barr virus infection, rotavirus infection, adenovirus infection, influenza A virus infection, respiratory syncytial virus infection, varicella-zoster virus infections, small pox infection, monkey pox infection and SARS infection.

138. The method of claim 134, wherein the fungal infection is selected from the group consisting of candidiasis, ringworm, histoplasmosis, blastomycosis, paracoccidioidomycosis, crytococcosis, aspergillosis, chromomycosis, mycetoma infections, pseudallescheriasis, and tinea versicolor infection.

139. The method of claim 134, wherein the parasite infection is selected from the group consisting of amebiasis, Trypanosoma cruzi infection, Fascioliasis, Leishmaniasis, Plasmodium infections, Onchocerciasis, Paragonimiasis, Trypanosoma brucei infection, Pneumocystis infection, Trichomonas vaginalis infection, Taenia infection, Hymenolepsis infection, Echinococcus infections, Schistosomiasis, neurocysticercosis, Necator americanus infection, and Trichuris trichuria infection.

140. The method of claim 112 or 129, wherein the agent of Formula I is administered in a route of administration different from that of the antigen.

141. The method of claim 129, further comprising administering an adjuvant to the subject.

142. The method of claim 141, wherein the adjuvant is selected from the group consisting of alum, cholera toxin, CpG immunostimulatory nucleic acids, MPL, MPD, and QS-21.

143. The method of claim 129, wherein the antigen is targeted to a tissue or a cell.

144. The method of claim 129, wherein the antigen is a cancer antigen.

145. The method of claim 144, further comprising treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

146. The method of claim 145, wherein the agent of Formula I and the antigen are administered prior to treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

147. The method of claim 145, wherein the agent of Formula I and the antigen are administered after treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

148. The method of claim 145, wherein the agent of Formula I and the antigen are administered prior to and after treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

149. The method of claim 144, wherein the agent of Formula I is administered to the subject prior to the antigen.

150. The method of claim 149, wherein the agent of Formula I is administered to the subject 30 minutes to 8 hours prior to administration of the antigen.

151. The method of claim 144, wherein the agent of Formula I is administered to the subject 1 to 7 days prior to administration of the antigen.

152. The method of claim 144, wherein the agent of Formula I is administered to the subject after administration of the antigen.

153. The method of claim 152, wherein the agent of Formula I is administered to the subject 30 minutes to 8 hours after administration of the antigen.

154. The method of claim 152, wherein the agent of Formula I is administered to the subject 1 to 7 days after administration of the antigen.

155. The method of claim 129, wherein the immune response is an antigen specific immune response.

156. The method of claim 129, wherein the immune response is an innate immune response or an adaptive immune response.

157. The method of claim 129, wherein the antigen is a microbial antigen.

158. The method of claim 157, wherein the microbial antigen is selected from the group consisting of a bacterial antigen, a mycobacterial antigen, a viral antigen, a fungal antigen, and a parasitic antigen.

159. The method of claim 158, wherein the bacterial antigen is derived from a bacterial species selected from the group consisting of E. coli, Staphylococcal, Streptococcal, Pseudomonas, Clostridium difficile, Legionella, Pneumococcus, Haemophilus, Klebsiella, Enterobacter, Citrobacter, Neisseria, Shigella, Salmonella, Listeria, Pasteurella, Streptobacillus, Spirillum, Treponema, Actinomyces, Borrelia, Corynebacterium, Nocardia, Gardnerella, Campylobacter, Spirochaeta, Proteus, Bacteriodes, H. pylori, and anthrax.

160. The method of claim 158, wherein the viral antigen is derived from a viral species selected from the group consisting of HIV, Herpes simplex virus 1, Herpes simplex virus 2, cytomegalovirus, hepatitis A virus, hepatitis B virus, hepatitis C virus, human papilloma virus, Epstein Barr virus, rotavirus, adenovirus, influenza A virus, respiratory syncytial virus, varicella-zoster virus, small pox, monkey pox and SARS.

161. The method of claim 158, wherein the fungal antigen is derived from a fungal species that causes an infection selected from the group consisting of candidiasis, ringworm, histoplasmosis, blastomycosis, paracoccidioidomycosis, crytococcosis, aspergillosis, chromomycosis, mycetoma infections, pseudallescheriasis, and tinea versicolor infection.

162. The method of claim 158, wherein the parasitic antigen is derived from a parasite species selected from the group consisting of amebiasis, Trypanosoma cruzi, Fascioliasis, Leishmaniasis, Plasmodium, Onchocerciasis, Paragonimiasis, Trypanosoma brucei, Pneumocystis, Trichomonas vaginalis, Taenia, Hymenolepsis, Echinococcus, Schistosomiasis, neurocysticercosis, Necator americanus, and Trichuris trichuria.

163. The method of claim 158, wherein the mycobacterial antigen is derived from a mycobacterial species selected from the group consisting of M. tuberculosis and M. leprae.

164. A method of preventing an infectious disease in a subject at risk of developing an infectious disease comprising

identifying a subject at risk of developing an infectious disease, and

administering an agent of Formula I to the subject in an amount effective to induce IL-1,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

165. The method of claim 164, further comprising administering to the subject a microbial antigen.

166. The method of claim 165, wherein the microbial antigen is selected from the group consisting of a bacterial antigen, a mycobacterial antigen, a viral antigen, a fungal antigen, and a parasitic antigen.

167. The method of claim 166, wherein the bacterial antigen is derived from a bacterial species selected from the group consisting of E. coli, Staphylococcal, Streptococcal, Pseudomonas, Clostridium difficile, Legionella, Pneumococcus, Haemophilus, Klebsiella, Enterobacter, Citrobacter, Neisseria, Shigella, Salmonella, Listeria, Pasteurella, Streptobacillus, Spirillum, Treponema, Actinomyces, Borrelia, Corynebacterium, Nocardia, Gardnerella, Campylobacter, Spirochaeta, Proteus, Bacteriodes, H. pylori, and anthrax.

168. The method of claim 166, wherein the viral antigen is derived from a viral species selected from the group consisting of HIV, Herpes simplex virus 1, Herpes simplex virus 2,

cytomegalovirus, hepatitis A virus, hepatitis B virus, hepatitis C virus, human papilloma virus, Epstein Barr virus, rotavirus, adenovirus, influenza A virus, respiratory syncytial virus, varicella-zoster virus, small pox, monkey pox and SARS.

169. The method of claim 166, wherein the fungal antigen is derived from a fungal species that causes an infection selected from the group consisting of candidiasis, ringworm, histoplasmosis, blastomycosis, paracoccidioidomycosis, crytococcosis, aspergillosis, chromomycosis, mycetoma infections, pseudallescheriasis, and tinea versicolor infection.

170. The method of claim 166, wherein the parasitic antigen is derived from a parasite species selected from the group consisting of amebiasis, Trypanosoma cruzi, Fascioliasis, Leishmaniasis, Plasmodium, Onchocerciasis, Paragonimiasis, Trypanosoma brucei, Pneumocystis, Trichomonas vaginalis, Taenia, Hymenolepsis, Echinococcus, Schistosomiasis, neurocysticercosis, Necator americanus, and Trichuris trichuria.

171. The method of claim 166, wherein the mycobacterial antigen is derived from a mycobacterial species selected from the group consisting of M. tuberculosis and M. leprae.

172. A method for stimulating an immune response in a subject having or at risk of having cancer comprising

administering to a subject in need of immune stimulation an agent of Formula I, and an antigen, in an amount effective to stimulate an antigen-specific immune response,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

173. The method of claim 172, wherein the subject is a subject having cancer.

174. The method of claim 172, wherein the subject has or is at risk of developing an infectious disease.

175. The method of claim 172, wherein the agent of Formula I is administered in a route of administration different from that of the antigen.

176. The method of claim 172, further comprising administering an adjuvant to the subject.

177. The method of claim 176, wherein the adjuvant is selected from the group consisting of alum, cholera toxin, CpG immunostimulatory nucleic acids, MPL, MPD, and QS-21.

178. The method of claim 172, wherein the antigen is a cancer antigen.

179. The method of claim 172, further comprising treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

180. The method of claim 179, wherein the agent of Formula I and the antigen are administered prior to treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

181. The method of claim 179, wherein the agent of Formula I and the antigen are administered after treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

182. The method of claim 179, wherein the agent of Formula I and the antigen are administered before and after treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

183. The method of claim 172, wherein the subject has not undergone an anti-cancer therapy selected from the group consisting of surgery, radiation and chemotherapy.

184. The method of claim 172, wherein the agent of Formula I is administered to the subject before the antigen.

185. The method of claim 184, wherein the agent of Formula I is administered to the subject 30 minutes to 8 hours before administration of the antigen.

186. The method of claim 184, wherein the agent of Formula I is administered to the subject 1 to 7 days before administration of the antigen.

187. The method of claim 172, wherein the agent of Formula I is administered to the subject after the antigen.

188. The method of claim 187, wherein the agent of Formula I is administered to the subject 30 minutes to 8 hours after administration of the antigen.

189. The method of claim 187, wherein the agent of Formula I is administered to the subject 1 to 7 days after administration of the antigen.

190. The method of claim 172, wherein the immune response is an antigen specific immune response.

191. The method of claim 172, wherein the immune response is an innate immune response or an adaptive immune response.

192. A method for stimulating an immune response in a non-immunocompromised subject comprising

administering to a subject in need thereof an agent of Formula I, in an amount effective to induce IL-1,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

193. The method of claim 192, wherein the subject is a subject having or at risk of developing cancer.

194. The method of claim 192, further comprising administering to the subject an antibody or antibody fragment.

195. The method of claim 192, wherein the subject is elderly.

196. The method of claim 192, wherein the subject is at risk of developing influenza.

197. The method of claim 192, wherein the subject is at risk of angina.

198. A method for stimulating an immune response in an immunocompromised subject comprising

administering to a subject in need thereof an agent of Formula I, in an amount effective to induce IL-1,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

199. The method of claim 198, wherein the immunocompromised subject is genetically immunocompromised.

200. The method of claim 199, wherein the subject has a genetic deficiency selected from the group consisting of SCID, agammaglobulinemia, and CDG.

201. The method of claim 198, wherein the subject has an immunoglobulin deficiency that is common variable immunodeficiency.

202. The method of claim 198, wherein the subject is a subject having or at risk of developing cancer.

203. The method of claim 198, further comprising administering to the subject an antibody or antibody fragment.

204. The method of claim 194 or 203, wherein the antibody or antibody fragment is selected from the group consisting of trastuzumab, alemtuzumab (B cell chronic lymphocytic leukemia), gemtuzumab ozogamicin (CD33+ acute myeloid leukemia), hP67.6 (CD33+ acute myeloid leukemia), infliximab (inflammatory bowel disease and rheumatoid arthritis), etanercept (rheumatoid arthritis), rituximab, tositumomab, MDX-210, oregovomab, anti-EGF receptor mAb, MDX-447, anti-tissue factor protein (TF), (Sunol); ior-c5, c5, edrecolomab, ibritumomab tiuxetan, anti-idiotypic mAb mimic of ganglioside GD3 epitope, anti-HLA-Dr10 mAb, anti-CD33 humanized mAb, anti-CD52 humAb, anti-CD1 mAb (ior t6), MDX-22, celogovab, anti-17-1A mAb, bevacizumab, daclizumab, anti-TAG-72 (MDX-220), anti-idiotypic mAb mimic of high molecular weight proteoglycan (I-Mel-1), anti-idiotypic mAb mimic of high molecular weight proteoglycan (I-Mel-2), anti-CEA Ab, hmAbH11, anti-DNA or DNA-associated proteins (histones) mAb, Gliomab-H mAb, GNI-250 mAb, anti-CD22, CMA 676), anti-idiotypic human mAb to GD2 ganglioside, ior egf/r3, anti-ior c2 glycoprotein mAb, ior c5, anti-FLK-

2/FLT-3 mAb, anti-GD-2 bispecific mAb, antinuclear autoantibodies, anti-HLA-DR Ab, anti-CEA mAb, palivizumab, bevacizumab, alemtuzumab, BLyS-mAb, anti-VEGF2, anti-Trail receptor; B3 mAb, mAb BR96, breast cancer; and Abx-Cbl mAb.

205. The method of claim 192 or 198, further comprising administering to the subject an antigen.

206. The method of claim 205, wherein the antigen is a cancer antigen or a microbial antigen.

207. The method of claim 206, wherein the microbial antigen is selected from the group consisting of a bacterial antigen, a mycobacterial antigen, a viral antigen, a fungal antigen, and a parasitic antigen.

208. The method of claim 207, wherein the bacterial antigen is derived from a bacterial species selected from the group consisting of E. coli, Staphylococcal, Streptococcal, Pseudomonas, Clostridium difficile, Legionella, Pneumococcus, Haemophilus, Klebsiella, Enterobacter, Citrobacter, Neisseria, Shigella, Salmonella, Listeria, Pasteurella, Streptobacillus, Spirillum, Treponema, Actinomyces, Borrelia, Corynebacterium, Nocardia, Gardnerella, Campylobacter, Spirochaeta, Proteus, Bacteriodes, H. pylori, and anthrax.

209. The method of claim 207, wherein the viral antigen is derived from a viral species selected from the group consisting of HIV, Herpes simplex virus 1, Herpes simplex virus 2, cytomegalovirus, hepatitis A virus, hepatitis B virus, hepatitis C virus, human papilloma virus, Epstein Barr virus, rotavirus, adenovirus, influenza A virus, respiratory syncytial virus, varicella-zoster virus, small pox, monkey pox and SARS.

210. The method of claim 207, wherein the fungal antigen is derived from a fungal species that causes an infection selected from the group consisting of candidiasis, ringworm, histoplasmosis, blastomycosis, paracoccidioidomycosis, crytococcosis, aspergillosis, chromomycosis, mycetoma infections, pseudallescheriasis, and tinea versicolor infection.

211. The method of claim 207, wherein the parasitic antigen is derived from a parasite species selected from the group consisting of amebiasis, Trypanosoma cruzi, Fascioliasis, Leishmaniasis,

Plasmodium, Onchocerciasis, Paragonimiasis, Trypanosoma brucei, Pneumocystis, Trichomonas vaginalis, Taenia, Hymenolepsis, Echinococcus, Schistosomiasis, neurocysticercosis, Necator americanus, and Trichuris trichuria.

212. The method of claim 206, wherein the cancer antigen is selected from the group consisting of MART-1/Melan-A, gp100, adenosine deaminase-binding protein (ADAbp), FAP, cyclophilin b, colorectal associated antigen (CRC)--C017-1A/GA733, carcinoembryonic antigen (CEA), CAP-1, CAP-2, etv6, AML1, prostate specific antigen (PSA), PSA-1, PSA-2, PSA-3, prostate-specific membrane antigen (PSMA), T-cell receptor/CD3-zeta chain, HER 2, CD33, EGF receptor, HLA markers such as HLA-DR, CD52, CD1, CEA, CD22, GD2 ganglioside, FLK2/FLT3, VEGF, VEGFR and CD20.

213. The method of claim 206, wherein the cancer antigen is selected from the group consisting of MAGE-A1, MAGE-A2, MAGE-A3, MAGE-A4, MAGE-A5, MAGE-A6, MAGE-A7, MAGE-A8, MAGE-A9, MAGE-A10, MAGE-A11, MAGE-A12, MAGE-Xp2 (MAGE-B2), MAGE-Xp3 (MAGE-B3), MAGE-Xp4 (MAGE-B4), MAGE-C1, MAGE-C2, MAGE-C3, MAGE-C4, MAGE-C5).

214. The method of claim 206, wherein the cancer antigen is selected from the group consisting of GAGE-1, GAGE-2, GAGE-3, GAGE-4, GAGE-5, GAGE-6, GAGE-7, GAGE-8, GAGE-9.

215. The method of claim 206, wherein the cancer antigen is selected from the group consisting of BAGE, RAGE, LAGE-1, NAG, GnT-V, MUM-1, CDK4, tyrosinase, p53, MUC family, HER2/neu, p21ras, RCAS1, α-fetoprotein, E-cadherin, α-catenin, β-catenin, γ-catenin, p120ctn, $gp100^{Pmel117}$, PRAME, NY-ESO-1, cdc27, adenomatous polyposis coli protein (APC), fodrin, Connexin 37, Ig-idiotype, p15, gp75, GM2 ganglioside, GD2 ganglioside, human papilloma virus proteins, Smad family of tumor antigens, Imp-1, P1A, EBV-encoded nuclear antigen (EBNA)-1, brain glycogen phosphorylase, SSX-1, SSX-2 (HOM-MEL-40), SSX-1, SSX-4, SSX-5, SCP-1 and CT-7, and c-erbB-2.

216. The method of claim 192 or 198, wherein the subject will have a surgery.

217. The method of claim 192 or 198, wherein the subject has a skin abrasion from a trauma.

218. The method of claim 192 or 198, wherein the subject is traveling to a region in which a microbial infection is common.

219. The method of claim 205, wherein the agent of Formula I and the antigen are formulated together.

220. The method of claim 205, wherein the antigen is administered mucosally.

221. The method of claim 198, wherein the subject has been treated with an agent selected from the group consisting of a cox-1 inhibitor, a cox-2 inhibitor, and a steroid.

222. The method of claim 221, wherein the agent is celecoxib, rofecoxib, naproxen or aspirin.

223. The method of claim 221, wherein the subject is a substance abuse subject.

224. The method of claim 223, wherein the substance is selected from the group consisting of alcohol and intravenous drug.

225. The method of claim 198, wherein the subject has gingivitis, osteomyelitis, diabetes type I, diabetes type II, chronic granuloma, chronic hepatitis, and chronic EBV infection.

226. The method of claim 194 or 203, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cell surface molecule.

227. The method of claim 226, wherein the cell surface molecule is selected from the group consisting of HER 2, CD20, CD33, EGF receptor, HLA markers such as HLA-DR, CD52, CD1, CEA, CD22, GD2 ganglioside, FLK2/FLT3, VEGF, VEGFR.

228. The method of claim 194 or 203, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cancer antigen.

229. The method of claim 228, wherein the cancer antigen is selected from the group consisting of HER 2 (p185), CD20, CD33, GD3 ganglioside, GD2 ganglioside, carcinoembryonic antigen (CEA), CD22, milk mucin core protein, TAG-72, Lewis A antigen, ovarian associated antigens such as

OV-TL3 and MOv18, high Mr melanoma antigens recognized by antibody 9.2.27, HMFG-2, SM-3, B72.3, PR5C5, and PR4D2.

230. The method of claim 194 or 203, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a stromal cell molecule.

231. The method of claim 230, wherein the stromal cell molecule is selected from the group consisting of FAP and CD26.

232. The method of claim 194 or 203, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for an extracellular matrix molecule.

233. The method of claim 230, wherein the extracellular matrix molecule is selected from the group consisting of collagen, glycosaminoglycans (GAGs), proteoglycans, elastin, fibronectin and laminin.

234. The method of claim 194 or 203, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a tumor vasculature associated antigen.

235. The method of claim 234, wherein the tumor vasculature associated antigen is selected from the group consisting of endoglin, ELAM-1, VCAM-1, ICAM-1, ligand reactive with LAM-1, MHC class II antigens, aminophospholipids such as phosphatidylserine and phosphatidylethanolamine, VEGFR1 (Flt-1), VEGFR2 (KDR/Flk-1), and a complex of a growth factor and its receptor such as a complex of FGF and the FGFR or a complex of TGFβ and the TGFβR.

236. The method of claim 234, wherein the antibody or antibody specific for a tumor vasculature associated antigen is selected from the group consisting of TEC-4 and TEC-11, 2C3 (ATCC PTA 1595), GV39 and GV97.

237. The method of claim 194 or 203, wherein the antibody or antibody fragment is administered on a first day of a seven day cycle and the agent of Formula I is administered twice a day on day two through day seven.

238. The method of claim 237, wherein the seven day cycle is repeated twice, thrice, or four times.

239. The method of claim 237, wherein the seven day cycle is repeated for a month, two months, or three months.

240. The method of claim 207, wherein the mycobacterial antigen is derived from a mycobacterial species selected from the group consisting of M. tuberculosis and M. leprae.

241. The method of claim 194 or 203, wherein the antibody or antibody fragment is conjugated to a toxin derived from plant, fungus, or bacteria.

242. The method of claim 241, wherein the toxin is selected from the group consisting of A chain toxin, deglycosylated A chain toxin, ribosome inactivating protein, α-sarcin, aspergillin, restrictocin, ribonuclease, diptheria toxin and Pseudomonas exotoxin.

243. The method of claim 203, wherein the antibody or antibody fragment is conjugated to a chemotherapeutic agent or a radioisotope.

244. The method of claim 243, wherein the chemotherapeutic agent is selected from the group consisting of an anti-metabolite, an anthracycline, a vinca alkaloid, an antibiotic, an alkylating agent, and an epipodophyllotoxin.

245. The method of claim 192, 194, 198 or 203, wherein the cancer antigen is a gene or gene product thereof that has undergone chromosomal alteration.

246. The method of claim 245, wherein the gene product is an RNA or protein gene product.

247. The method of claim 245, wherein the gene or gene product that has undergone chromosomal alteration is selected from the group consisting of gene or gene products associated with activation of quiescent genes, and gene or gene products associated with a novel fusion gene and protein.

248. The method of claim 247, wherein the gene or gene products associated with activation of quiescent genes is selected from the group consisting of *BCL-1 and IgH, BCL-2 and IgH, BCL-6, TAL-1 and TCRδ or SIL, c-MYC and IgH or IgL, MUN/IRF4 and IgH* , and *PAX-5 (BSAP).*

249. The method of claim 247, wherein the gene or gene products associated with a novel fusion gene and protein is selected from the group consisting of *RARα, PML, PLZF, NPM or NuMA; BCR and ABL; MLL (HRX); E2A and PBX or HLF; NPM, ALK*; and *NPM, MLF-1.*

250. The method of claim 192, 194, 198 or 203, wherein the cancer antigen is a tissue- or lineage-specific antigen.

251. The method of claim 250, wherein the tissue- or lineage-specific antigen is a cell surface protein, epidermal growth factor receptor, cell-associated protein, or a secreted protein.

252. The method of claim 250, wherein the cell surface protein is selected from the group consisting of CD20, CD22, CD52, CD33, CD10 (gp100), CD3/T-cell receptor (TCR), CD79/B-cell receptor (BCR), CD26, Human leukocyte antigen (HLA)-DR, HLA-DP, and HLA-DQ, RCAS1, and Prostate specific membrane antigen.

253. The method of claim 250, wherein the epidermal growth factor receptor is selected from the group consisting of EGFR (HER1 or erbB1) and EGFRvIII, erbB2 (HER2 or HER2/neu), erbB3 (HER3), and erbB4 (HER4).

254. The method of claim 250, wherein the cell-associated protein is selected from the group consisting of Tyrosinase, Melan-A/MART-1, tyrosinase related protein (TRP)-1/gp75, Polymorphic epithelial mucin (PEM), and Human epithelial mucin (MUC1).

255. The method of claim 250, wherein the secreted protein is selected from the group consisting of monoclonal immunoglobulin, immunoglobulin light chains, α-fetoprotein, kallikreins 6 and 10, gastrin-releasing peptide/bombesin, and prostate specific antigen.

256. The method of claim 192, 194, 198 or 203, wherein the cancer antigen is a cancer testis (CT) antigen.

257. The method of claim 256, wherein the cancer testis (CT) antigen is selected from the group consisting of MAGE, MAGE-A1, -A3, -A6, -A12, MAGE-3, BAGE, GAGE, GAGE -1, -2, -3, -4, -5, -6, -7, and -8, HAGE, LAGE-1, NY-ESO-1, RAGE, RAGE-1, -2, -4, SSX, SSX-1, -2, -3, -4, -5, -6, -7, -8, -9, HOM-TES-14/SCP-1, HOM-TES-85, HOM-MEL-40, and PRAME.

258. The method of claim 192, 194, 198 or 203, wherein the cancer antigen is a non-tissue or non-lineage specific antigen.

259. The method of claim 258, wherein the non-tissue or non-lineage specific antigen is a carcinoembryonic antigen family member.

260. The method of claim 259, wherein the carcinoembryonic antigen family member is selected from the group consisting of CD66a, CD66b, CD66c, CD66d and CD66e.

261. The method of claim 192, 194, 198 or 203, wherein the cancer antigen is a viral protein.

262. The method of claim 261, wherein the viral protein is selected from the group consisting of Human papilloma virus protein, and EBV-encoded nuclear antigen (EBNA)-1.

263. The method of claim 192, 194, 198 or 203, wherein the cancer antigen is an antigen that is mutated or aberrantly expressed in a cancer.

264. The method of claim 263, wherein the antigen that is mutated or aberrantly expressed in a cancer is CDK4 or beta-catenin.

265. The method of claim 194 or 203, wherein the antibody or antibody fragment is selected from the group consisting of Avastin (bevacizumab), BEC2 (mitumomab), Bexxar (tositumomab), Campath (alemtuzumab), CeaVac, Herceptin (trastuzumab), IMC-C225 (centuximab), LymphoCide (epratuzumab), MDX-210, Mylotarg (gemtuzumab ozogamicin), Panorex (edrecolomab), Rituxan (rituximab), Theragyn (pemtumomab), Zamyl, and Zevalin (ibritumomab tituxetan).

266. The method of claim 192, 194, 198 or 203, wherein the cancer antigen is selected from the group consisting of VEGF, Anti-idiotypic mAb (GD3 ganglioside mimic), CD20, CD52, Anti-idiotypic mAb (CEA mimic), ERBB2, EGFR, CD22, ERBB2 X CD65 (fcγRI), CD33, EpCam, and PEM.

267. A method for treating a subject having or at risk of developing an IFN-responsive condition comprising

administering to a subject in need of such treatment an agent of Formula I in an amount effective to induce a therapeutically or prophylactically effective amount of IL-1 in the subject,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

268. The method of claim 267, wherein the IFN-responsive condition is a chronic infection selected from the group consisting of a chronic hepatitis B infection, chronic hepatitis C infection, chronic Epstein Barr Virus infection, and tuberculosis.

269. The method of claim 268, further comprising administering a second active agent selected from the group consisting of IFNα, pegylated IFN, IFNα-2b, acyclovir, lobucavir, ganciclovir, L-deoxythymidine, clevudine, a therapeutic vaccine, phosphonoformate (PFA), ribavirin (RBV), thymosin alpha-1, 2 3-dideoxy-3-fluoroguanosine (FLG), famciclovir, lamivudine, adefovir dipivoxil, entecavir, emtricitabine, and hepatitis B-specific immunoglobulin.

270. The method of claim 268, wherein the subject is HIV positive.

271. The method of claim 267, wherein the disorder has become drug resistant.

272. The method of claim 267, wherein the disorder is multiple sclerosis.

273. The method of claim 267, wherein IFN is selected from the group consisting of IFNα, IFNα-2b, IFNβ, IFN-γ.

274. The method of claim 267, wherein the IFN-responsive condition is an IFN-γ responsive condition.

275. The method of claim 274, wherein the IFN-γ responsive condition is selected from the group consisting of viral infections and associated diseases, and cancer.

276. A method for treating a subject having or at risk of developing cancer comprising administering to a subject in need of such treatment an enzyme inhibitor selected from the group consisting of a tyrosine kinase inhibitor, a CDK inhibitor, a MAP kinase inhibitor, and an EGFR inhibitor, and an agent of Formula I in an amount effective to inhibit the cancer,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

277. The method of claim 276, wherein the amount effective is a synergistic amount.

278. The method of claim 276, wherein the CDK inhibitor is selected from the group consisting of p21, p27, p57, p15, p16, p18, and p19.

279. The method of claim 276, wherein the MAP kinase inhibitor is selected from the group consisting of KY12420 ($C_{23}H_{24}O_8$), CNI-1493, PD98059, 4-(4-Fluorophenyl)-2-(4-methylsulfinyl phenyl)-5-(4-pyridyl) 1H-imidazole.

280. The method of claim 276, wherein the EGFR inhibitor is selected from the group consisting of Tarceva^{TM}(OSI-774), Iressa (ZD1839), WHI-P97 (quinazoline derivative), LFM-A12 (leflunomide metabolite analog), AG1458.

281. A method for treating a subject having or at risk of developing cardiovascular disease comprising

administering to a subject in need of such treatment an agent of Formula I in an amount effective to induce an effective amount of IL-1.

282. The method of claim 280, further comprising identifying the subject in need of such treatment.

283. A method for preventing drug resistance in a subject having an infectious disease comprising

administering to a subject receiving an anti-microbial agent, an agent of Formula I in an amount effective to reduce the risk of resistance to the anti-microbial agent,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

284. The method of claim 283, wherein the infectious disease is selected from the group consisting of a bacterial infection, a mycobacterial infection, a viral infection, a fungal infection and a parasitic infection.

285. The method of claim 283, wherein the bacterial infection is a Pseudomonas infection.

286. The method of claim 283, wherein the anti-microbial agent is selected from the group consisting of an anti-bacterial agent, an anti-mycobacterial agent, an anti-viral agent, an anti-fungal agent, and an anti-parasitic agent.

287. A method of shortening a vaccination course comprising

administering to a subject in need of immunization an agent of Formula I in an amount effective to induce an antigen-specific immune response to a vaccine administered in a vaccination course,

wherein the vaccination course is shortened by at least one immunization,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

288. The method of claim 287, wherein the vaccine is for hepatitis virus.

289 The method of claim 288, wherein hepatitis is hepatitis B virus.

290. A method of shortening a vaccination course comprising

administering to a subject in need of immunization an agent of Formula I in an amount effective to induce an antigen-specific immune response to a vaccine administered in a vaccination course,

wherein the vaccination course is shortened by at least one day,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

291. The method of claim 287 or 290, wherein the agent of Formula I is administered substantially simultaneously with the vaccine.

292. The method of claim 290, wherein the vaccine is for hepatitis virus.

293. The method of claim 292, wherein hepatitis virus is hepatitis B virus.

294. A method for stimulating an immune response in a subject having cancer comprising administering to a subject in need of such treatment an agent of Formula I in an amount effective to stimulate an antigen-specific immune response, prior to and following a therapy selected from the group consisting of radiation, surgery and chemotherapy,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

295. The method of claim 294, further comprising administering an adjuvant to the subject.

296. The method of claim 295, wherein the adjuvant is selected from the group consisting of alum, cholera toxin, CpG immunostimulatory nucleic acids, MPL, MPD, and QS-21.

297. The method of claim 294, wherein the agent of Formula I is administered to the subject 30 minutes to 8 hours before the therapy and 30 minutes to 8 hours after the therapy.

298. The method of claim 294, wherein the agent of Formula I is administered in a dose of greater than 10^{-8}M.

299. A method for stimulating an immune response in a subject at risk of developing cancer comprising

administering to a subject in need of such treatment an agent of Formula I in an amount effective to stimulate an antigen-specific immune response,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

300. The method of claim 299, further comprising identifying a subject in need of such treatment.

301. The method of claim 299, wherein the subject at risk of developing cancer has a familial predisposition to developing cancer.

302. The method of claim 301, wherein the familial predisposition is familial colon polyposis.

303. The method of claim 299, wherein the subject has precancerous polyps.

304. The method of claim 299, wherein the subject has precancerous HPV lesions.

305. The method of claim 299, wherein the subject is at risk of developing a cancer that is a metastasis.

306. The method of claim 299, further comprising administering an adjuvant to the subject.

307. The method of claim 306, wherein the adjuvant is selected from the group consisting of alum, cholera toxin, CpG immunostimulatory nucleic acids, MPL, MPD, and QS-21.

308. The method of claim 299, wherein the agent of Formula I is administered in a dose of greater than 10^{-8}M.

309. A method for modulating an immune response comprising

administering to a subject in need thereof an antibody or an antibody fragment on a first day of a seven day cycle, and administering to the subject an agent of Formula I on day 2 through to day 7 of the seven day cycle,

wherein the agent of Formula I is administered by injection or in an enterically coated form.

310. The method of claim 309, wherein the agent is administered twice a day on day 2 through to day 7.

311. The method of claim 309, wherein the seven day cycle is repeated twice, thrice, or four times.

312. The method of claim 309, wherein the seven day cycle is repeated for a month or two months.

313. The method of claim 309, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cell surface molecule.

314. The method of claim 313, wherein the cell surface molecule is selected from the group consisting of HER 2, CD20, CD33, EGF receptor, HLA markers such as HLA-DR, CD52, CD1, CEA, CD22, GD2 ganglioside, FLK2/FLT3, VEGF, VEGFR.

315. The method of claim 309, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cancer antigen.

316. The method of claim 315, wherein the cancer antigen is selected from the group consisting of HER 2 (p185), CD20, CD33, GD3 ganglioside, GD2 ganglioside, carcinoembryonic antigen (CEA), CD22, milk mucin core protein, TAG-72, Lewis A antigen, ovarian associated antigens such as OV-TL3 and MOv18, high Mr melanoma antigens recognized by antibody 9.2.27, HMFG-2, SM-3, B72.3, PR5C5, PR4D2.

317. The method of claim 309, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a stromal cell molecule.

318. The method of claim 317, wherein the stromal cell molecule is selected from the group consisting of FAP and CD26.

319. The method of claim 309, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for an extracellular matrix molecule.

320. The method of claim 578, wherein the extracellular matrix molecule is selected from the group consisting of collagen, glycosaminoglycans (GAGs), proteoglycans, elastin, fibronectin and laminin.

321. The method of claim 315, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a tumor vasculature associated antigen.

322. The method of claim 321, wherein the tumor vasculature associated antigen is selected from the group consisting of endoglin, ELAM-1, VCAM-1, ICAM-1, ligand reactive with LAM-1, MHC class II antigens, aminophospholipids such as phosphatidylserine and phosphatidylethanolamine, VEGFR1 (Flt-1), VEGFR2 (KDR/Flk-1), a complex of a growth factor and its receptor such as a complex of FGF and the FGFR or a complex of TGFβ and the TGFβR.

323. The method of claim 321, wherein the antibody or antibody specific for a tumor vasculature associated antigen is selected from the group consisting of TEC-4 and TEC-11, 2C3 (ATCC PTA 1595), GV39 and GV97.

324. The method of claim 315, wherein the antibody or antibody fragment is conjugated to a toxin derived from plant, fungus, or bacteria.

325. The method of claim 324, wherein the toxin is selected from the group consisting of A chain toxin, deglycosylated A chain toxin, ribosome inactivating protein, α-sarcin, aspergillin, restrictocin, ribonuclease, diptheria toxin and Pseudomonas exotoxin.

326. The method of claim 315, wherein the antibody or antibody fragment is conjugated to a chemotherapeutic agent, a radioisotope or a cytotoxin.

327. The method of claim 326, wherein the chemotherapeutic agent is selected from the group consisting of an anti-metabolite, an anthracycline, a vinca alkaloid, an antibiotic, an alkylating agent, and an epipodophyllotoxin.

328. The method of claim 206 or 315, wherein the cancer antigen is a gene or gene product thereof that has undergone chromosomal alteration.

329. The method of claim 328, wherein the gene product is an RNA or protein gene product.

330. The method of claim 328, wherein the gene or gene product that has undergone chromosomal alteration is selected from the group consisting of gene or gene products associated with activation of quiescent genes, and gene or gene products associated with a novel fusion gene and protein.

331. The method of claim 330, wherein the gene or gene products associated with activation of quiescent genes is selected from the group consisting of *BCL-1 and IgH, BCL-2 and IgH, BCL-6, TAL-1 and TCRδ or SIL, c-MYC and IgH or IgL, MUN/IRF4 and IgH,* and *PAX-5 (BSAP).*

332. The method of claim 330, wherein the gene or gene products associated with a novel fusion gene and protein is selected from the group consisting of *RARα, PML, PLZF, NPM or NuMA, BCR and ABL, MLL (HRX), E2A and PBX or HLF, NPM, ALK,* and *NPM, MLF-1.*

333. The method of claim 206 or 315, wherein the cancer antigen is a tissue- or lineage-specific antigen.

334. The method of claim 33, wherein the tissue- or lineage-specific antigen is a cell surface protein, epidermal growth factor receptor, cell-associated protein, or a secreted protein.

335. The method of claim 334, wherein the cell surface protein is selected from the group consisting of CD20, CD22, CD52, CD33, CD10 (gp100), CD3/T-cell receptor (TCR), CD79/B-cell receptor (BCR), CD26, Human leukocyte antigen (HLA)-DR, HLA-DP, and HLA-DQ, RCAS1, and Prostate specific membrane antigen.

336. The method of claim 334, wherein the epidermal growth factor receptor is selected from the group consisting of EGFR (HER1 or erbB1) and EGFRvIII, erbB2 (HER2 or HER2/neu), erbB3 (HER3), and erbB4 (HER4).

337. The method of claim 334, wherein the cell-associated protein is selected from the group consisting of Tyrosinase, Melan-A/MART-1, tyrosinase related protein (TRP)-1/gp75, Polymorphic epithelial mucin (PEM), and Human epithelial mucin (MUC1).

338. The method of claim 334, wherein the secreted protein is selected from the group consisting of Monoclonal immunoglobulin, Immunoglobulin light chains, α-fetoprotein, Kallikreins 6 and 10, Gastrin-releasing peptide/bombesin, and Prostate specific antigen.

339. The method of claim 206 or 315, wherein the cancer antigen is a cancer testis (CT) antigen.

340. The method of claim 339, wherein the cancer testis (CT) antigen is selected from the group consisting of MAGE, MAGE-A1, -A3, -A6, -A12, MAGE-3, BAGE, GAGE, GAGE -1, -2, -3, -4, -5, -6, -7, and -8, HAGE, LAGE-1, NY-ESO-1, RAGE, RAGE-1, -2, -4, SSX, SSX-1, -2, -3, -4, -5, -6, -7, -8, -9, HOM-TES-14/SCP-1, HOM-TES-85, HOM-MEL-40, and PRAME.

341. The method of claim 206 or 315, wherein the cancer antigen is a non-tissue or non-lineage specific antigen.

342. The method of claim 341, wherein the non-tissue or non-lineage specific antigen is a carcinoembryonic antigen family member.

343. The method of claim 342, wherein the carcinoembryonic antigen family member is selected from the group consisting of CD66a, CD66b, CD66c, CD66d and CD66e.

344. The method of claim 206 or 315, wherein the cancer antigen is a viral protein.

345. The method of claim 344, wherein the viral protein is selected from the group consisting of Human papilloma virus protein and EBV-encoded nuclear antigen (EBNA)-1.

346. The method of claim 206 or 315, wherein the cancer antigen is an antigen that is mutated or aberrantly expressed in a cancer.

347. The method of claim 346, wherein the antigen that is mutated or aberrantly expressed in a cancer is CDK4 or beta-catenin.

348. The method of claim 206 or 315, wherein the cancer antigen is selected from the group consisting of VEGF, Anti-idiotypic mAb (GD3 ganglioside mimic), CD20, CD52, Anti-idiotypic mAb (CEA mimic), ERBB2, EGFR, CD22, ERBB2 X CD65 (fcγRI), CD33, EpCam, and PEM.

349. The method of claim 2, 172, 294, or 299, wherein the cancer is selected from the group consisting of basal cell carcinoma, biliary tract cancer; bladder cancer; bone cancer; brain cancer; breast cancer; cervical cancer; choriocarcinoma; CNS cancer; colon and rectum cancer; connective tissue cancer;

cancer of the digestive system; endometrial cancer; esophageal cancer; eye cancer; cancer of the head and neck; gastric cancer; intra-epithelial neoplasm; kidney cancer; larynx cancer; leukemia; chronic myeloid leukemia, chronic lymphoid leukemia, acute myeloid leukemia, acute lymphoid leukemia, liver cancer; small cell lung cancer; non-small cell lung cancer; lymphoma, Hodgkin's lymphoma; Non-Hodgkin's lymphoma; melanoma; myeloma; neuroblastoma; oral cavity cancer; ovarian cancer; pancreatic cancer; prostate cancer; retinoblastoma; rhabdomyosarcoma; rectal cancer; renal cancer; cancer of the respiratory system; sarcoma; skin cancer; stomach cancer; testicular cancer; thyroid cancer; uterine cancer; and cancer of the urinary system.

350. The method of claim 2, 172, 294, or 299, wherein the cancer is selected from the group consisting of a lymphoma or leukemia.

351. The method of claim 2, 172, 294, or 299, wherein the cancer is selected from the group consisting of bladder cancer, breast cancer, colon cancer, endometrial cancer, head and neck cancer, leukemia, lung cancer, lymphoma, melanoma, ovarian cancer, prostate cancer and rectal cancer.

352. The method of claim 2, 172, 294, or 299, wherein the cancer is a refractory cancer.

353. The method of claim 2, 172, 294, or 299, wherein the refractory cancer is melanoma, renal cell carcinoma, pancreatic cancer, colon cancer, hepatic cancer, lung cancer, Non-Hodgkin's lymphoma or leukemia.

354. The method of claim 2, 172, 294, or 299, wherein the cancer is a metastasis.

355. The method of claim 13, 164 or 174, wherein the infectious disease is a bacterial infection, a viral infection, a fungal infection, a parasitic infection or a mycobacterial infection.

356. The method of claim 14, wherein the bacterial infection is selected from the group consisting of an E. coli infection, a Staphylococcal infection, a Streptococcal infection, a Pseudomonas infection, Clostridium difficile infection, Legionella infection, Pneumococcus infection, Haemophilus infection, Klebsiella infection, Enterobacter infection, Citrobacter infection, Neisseria infection, Shigella infection, Salmonella infection, Listeria infection, Pasteurella infection, Streptobacillus infection, Spirillum infection, Treponema infection, Actinomyces infection, Borrelia infection, Corynebacterium

infection, Nocardia infection, Gardnerella infection, Campylobacter infection, Spirochaeta infection, Proteus infection, Bacteriodes infection, H. pylori infection, and anthrax infection.

357. The method of claim 14, wherein the viral infection is selected from the group consisting of an HIV infection, a Herpes simplex virus 1 infection, a Herpes simplex virus 2 infection, cytomegalovirus infection, hepatitis A virus infection, hepatitis B virus infection, hepatitis C virus infection, human papilloma virus infection, Epstein Barr virus infection, rotavirus infection, adenovirus infection, influenza A virus infection, respiratory syncytial virus infection, varicella-zoster virus infections, small pox infection, SARS infection, or monkey pox infection.

358. The method of claim 14, wherein the fungal infection is selected from the group consisting of candidiasis, ringworm, histoplasmosis, blastomycosis, paracoccidioidomycosis, crytococcosis, aspergillosis, chromomycosis, mycetoma infections, pseudallescheriasis, and tinea versicolor infection.

359. The method of claim 14, wherein the parasitic infection is selected from the group consisting of amebiasis, Trypanosoma cruzi infection, Fascioliasis, Leishmaniasis, Plasmodium infections, Onchocerciasis, Paragonimiasis, Trypanosoma brucei infection, Pneumocystis infection, Trichomonas vaginalis infection, Taenia infection, Hymenolepsis infection, Echinococcus infections, Schistosomiasis, neurocysticercosis, Necator americanus infection, and Trichuris trichuria infection.

360. The method of claim 14, wherein the viral infection is selected from the group consisting of a Herpes simplex virus 1 infection, a Herpes simplex virus 2 infection, cytomegalovirus infection, hepatitis A virus infection, hepatitis B virus infection, hepatitis C virus infection, human papilloma virus infection, Epstein Barr virus infection, rotavirus infection, adenovirus infection, influenza A virus infection, respiratory syncytial virus infection, varicella-zoster virus infections, small pox infection, monkey pox infection and SARS infection.

361. The method of claim 14 wherein the mycobacterial infection is selected from the group consisting of tuberculosis and leprosy.

362. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein the agent of Formula I is an agent of Formula II.

363. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568 wherein the agent of Formula I is an agent of Formula III.

364. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein the agent of Formula I is Ile-boroPro.

365. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein injection is subcutaneous injection.

366. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein injection is intravenous injection, intramuscular injection, intraperitoneal injection, or intra-tumor injection.

367. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein the enterically coated form is a pill, a capsule or a tablet.

368. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein the effective amount is about 0.005 mg/kg to less than 1.0 mg/kg body weight per day.

369. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein the agent of Formula I is at least 96% pure L-isomer.

370. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein the subject is experiencing nausea.

371. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein the subject is intolerant of Val-boroPro.

372. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein the subject is otherwise free of symptoms calling for hemopoietic stimulation.

373. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein the subject has normal hemopoietic activity.

374. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein the subject is HIV negative.

375. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein the agent of Formula I is administered on a routine schedule.

376. The method of claim 1, 13, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309 or 568, wherein the subject is first administered proline boropro.

377. The method of claim 1, 13, 112, 129, 172, 276, 283, 287, 290, 294, 299 or 309, wherein the agent of Formula I is administered in an amount that increases lymphoid tissue levels of IL-1, G-CSF or IL-8.

378. The method of claim 1, 13, 112, 129, 172, 276, 283, 287, 290, 294, 299 or 309, wherein the agent of Formula I is administered in an amount that does not increase serum IL-1 levels.

379. The method of claim 377, wherein the IL-1 is IL-1α or IL-1β.

380. The method of claim 378, wherein the IL-1 is IL-1α or IL-1β.

381. The method of claim 164, 192, 198, 267 or 281, wherein the IL-1 is IL-1α or IL-1β.

382. The method of claim 112, 194, 203 or 309, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cell surface molecule.

383. The method of claim 382, wherein the cell surface molecule is selected from the group consisting of HER 2, CD20, CD33, EGF receptor, HLA markers such as HLA-DR, CD52, CD1, CEA, CD22, GD2 ganglioside, FLK2/FLT3, VEGF and VEGFR .

384. The method of claim 112, 194, 203 or 309, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cancer antigen.

385. The method of claim 384, wherein the cancer antigen is selected from the group consisting of HER 2 (p185), CD20, CD33, GD3 ganglioside, GD2 ganglioside, carcinoembryonic antigen (CEA), CD22, milk mucin core protein, TAG-72, Lewis A antigen, ovarian associated antigens such as OV-TL3 and MOv18, high Mr melanoma antigens recognized by antibody 9.2.27, HMFG-2, SM-3, B72.3, PR5C5 and PR4D2.

386. The method of claim 112, 194, 203 or 309, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a stromal cell molecule.

387. The method of claim 386, wherein the stromal cell molecule is selected from the group consisting of FAP and CD26.

388. The method of claim 112, 194, 203 or 309, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for an extracellular matrix molecule.

389. The method of claim 388, wherein the extracellular matrix molecule is selected from the group consisting of collagen, glycosaminoglycans (GAGs), proteoglycans, elastin, fibronectin and laminin.

390. The method of claim 112, 194, 203 or 309, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a tumor vasculature associated antigen.

391. The method of claim 390, wherein the tumor vasculature associated antigen is selected from the group consisting of endoglin, ELAM-1, VCAM-1, ICAM-1, ligand reactive with LAM-1, MHC class II antigens, aminophospholipids such as phosphatidylserine and phosphatidylethanolamine, VEGFR1 (Flt-1), VEGFR2 (KDR/Flk-1), and a complex of a growth factor and its receptor such as a complex of FGF and the FGFR or a complex of TGFβ and the TGFβR.

392. The method of claim 390, wherein the antibody or antibody specific for a tumor vasculature associated antigen is selected from the group consisting of TEC-4 and TEC-11, 2C3 (ATCC PTA 1595), GV39 and GV97.

393. The method of claim 112, 194, 203 or 309, wherein the antibody or antibody fragment is administered on a first day of a seven day cycle and the agent of Formula I is administered twice a day on day two through day seven.

394. The method of claim 393, wherein the seven day cycle is repeated twice, thrice, or four times.

395. The method of claim 393, wherein the seven day cycle is repeated for a month, two months, or three months.

396. The method of claim 112, 194, 203 or 309, wherein the antibody or antibody fragment is conjugated to a toxin derived from plant, fungus, or bacteria.

397. The method of claim 396, wherein the toxin is selected from the group consisting of A chain toxin, deglycosylated A chain toxin, ribosome inactivating protein, α-sarcin, aspergillin, restrictocin, ribonuclease, diptheria toxin and Pseudomonas exotoxin.

398. The method of claim 112, 194, 203 or 309, wherein the antibody or antibody fragment is conjugated to a chemotherapeutic agent or a radioisotope.

399. The method of claim 398, wherein the chemotherapeutic agent is selected from the group consisting of an anti-metabolite, an anthracycline, a vinca alkaloid, an antibiotic, an alkylating agent, and an epipodophyllotoxin.

400. The method of claim 112, 194, 203 or 309, wherein the antibody or antibody fragment is selected from the group consisting of Avastin (bevacizumab), BEC2 (mitumomab), Bexxar (tositumomab), Campath (alemtuzumab), CeaVac, Herceptin (trastuzumab), IMC-C225 (centuximab), LymphoCide (epratuzumab), MDX-210, Mylotarg (gemtuzumab ozogamicin), Panorex (edrecolomab), Rituxan (rituximab), Theragyn (pemtumomab), Zamyl, and Zevalin (ibritumomab tituxetan).

401. The method of claim 144, 178, 206 or 315, wherein the cancer antigen is selected from the group consisting of MART-1/Melan-A, gp100, adenosine deaminase-binding protein (ADAbp), FAP, cyclophilin b, colorectal associated antigen (CRC)--C017-1A/GA733, carcinoembryonic antigen (CEA), CAP-1, CAP-2, etv6, AML1, prostate specific antigen (PSA), PSA-1, PSA-2, PSA-3, prostate-specific membrane antigen (PSMA), T-cell receptor/CD3-zeta chain, and CD20.

402. The method of claim 144, 178, 206 or 315, wherein the cancer antigen is selected from the group consisting of MAGE-A1, MAGE-A2, MAGE-A3, MAGE-A4, MAGE-A5, MAGE-A6, MAGE-A7, MAGE-A8, MAGE-A9, MAGE-A10, MAGE-A11, MAGE-A12, MAGE-Xp2 (MAGE-B2), MAGE-Xp3 (MAGE-B3), MAGE-Xp4 (MAGE-B4), MAGE-C1, MAGE-C2, MAGE-C3, MAGE-C4, MAGE-C5).

403. The method of claim 144, 178, 206 or 315, wherein the cancer antigen is selected from the group consisting of GAGE-1, GAGE-2, GAGE-3, GAGE-4, GAGE-5, GAGE-6, GAGE-7, GAGE-8, GAGE-9.

404. The method of claim 144, 178, 206 or 315, wherein the cancer antigen is selected from the group consisting of BAGE, RAGE, LAGE-1, NAG, GnT-V, MUM-1, CDK4, tyrosinase, p53, MUC family, HER2/neu, p21ras, RCAS1, α-fetoprotein, E-cadherin, α-catenin, β-catenin, γ-catenin, p120ctn, $gp100^{Pmel117}$, PRAME, NY-ESO-1, cdc27, adenomatous polyposis coli protein (APC), fodrin, Connexin 37, Ig-idiotype, p15, gp75, GM2 ganglioside, GD2 ganglioside, human papilloma virus proteins, Smad family of tumor antigens, Imp-1, P1A, EBV-encoded nuclear antigen (EBNA)-1, brain glycogen phosphorylase, SSX-1, SSX-2 (HOM-MEL-40), SSX-1, SSX-4, SSX-5, SCP-1 and CT-7, and c-erbB-2.

405. A composition comprising

an effective amount of an agent of Formula I and an antibody or antibody fragment,

wherein the agent of Formula I is formulated for administration by injection or in an enterically coated form.

406. The composition of claim 405, further comprising a pharmaceutically acceptable carrier.

407. The composition of claim 405, wherein the effective amount is an amount to stimulate antibody dependent cell-mediated cytoxicity.

408. The composition of claim 405, wherein the effective amount is an amount to treat or prevent cancer.

409. The composition of claim 405, wherein the effective amount is an amount to treat or prevent an infectious disease.

410. The composition of claim 405, wherein the antibody or antibody fragment is an antibody.

411. The composition of claim 405, wherein the antibody or antibody fragment is selected from the group consisting of trastuzumab, alemtuzumab (B cell chronic lymphocytic leukemia), gemtuzumab ozogamicin (CD33+ acute myeloid leukemia), hP67.6 (CD33+ acute myeloid leukemia), infliximab (inflammatory bowel disease and rheumatoid arthritis), etanercept (rheumatoid arthritis), rituximab, tositumomab, MDX-210, oregovomab, anti-EGF receptor mAb, MDX-447, anti-tissue factor protein (TF), (Sunol); ior-c5, c5, edrecolomab, ibritumomab tiuxetan, anti-idiotypic mAb mimic of ganglioside GD3 epitope, anti-HLA-Dr10 mAb, anti-CD33 humanized mAb, anti-CD52 humAb, anti-CD1 mAb (ior t6), MDX-22, celogovab, anti-17-1A mAb, bevacizumab, daclizumab, anti-TAG-72 (MDX-220), anti-idiotypic mAb mimic of high molecular weight proteoglycan (I-Mel-1), anti-idiotypic mAb mimic of high molecular weight proteoglycan (I-Mel-2), anti-CEA Ab, hmAbH11, anti-DNA or DNA-associated proteins (histones) mAb, Gliomab-H mAb, GNI-250 mAb, anti-CD22, CMA 676), anti-idiotypic human mAb to GD2 ganglioside, ior egf/r3, anti-ior c2 glycoprotein mAb, ior c5, anti-FLK-2/FLT-3 mAb, anti-GD-2 bispecific mAb, antinuclear autoantibodies, anti-HLA-DR Ab, anti-CEA mAb, palivizumab, bevacizumab, alemtuzumab, BLyS-mAb, anti-VEGF2, anti-Trail receptor; B3 mAb, mAb BR96, breast cancer; and Abx-Cbl mAb.

412. The composition of claim 405, wherein the antibody or antibody fragment is an anti-HER2 antibody.

413. The composition of claim 412, wherein the anti-HER2 antibody is trastuzumab.

414. The composition of claim 405, wherein the antibody or antibody fragment is an anti-CD20 antibody.

415. The composition of claim 414, wherein the anti-CD20 antibody is rituximab.

416. The composition of claim 405, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cell surface molecule.

417. The composition of claim 416, wherein the cell surface molecule is selected from the group consisting of HER 2, CD20, CD33, EGF receptor, HLA markers such as HLA-DR, CD52, CD1, CEA, CD22, GD2 ganglioside, FLK2/FLT3, VEGF, and VEGFR.

418. The composition of claim 405, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cancer antigen.

419. The composition of claim 418, wherein the cancer antigen is selected from the group consisting of HER 2 (p185), CD20, CD33, GD3 ganglioside, GD2 ganglioside, carcinoembryonic antigen (CEA), CD22, milk mucin core protein, TAG-72, Lewis A antigen, ovarian associated antigens such as OV-TL3 and MOv18, high Mr melanoma antigens recognized by antibody 9.2.27, HMFG-2, SM-3, B72.3, PR5C5, and PR4D2.

420. The composition of claim 405, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a stromal cell molecule.

421. The composition of claim 420, wherein the stromal cell molecule is selected from the group consisting of FAP and CD26.

422. The composition of claim 405, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for an extracellular matrix molecule.

423. The composition of claim 422, wherein the extracellular matrix molecule is selected from the group consisting of collagen, glycosaminoglycans (GAGs), proteoglycans, elastin, fibronectin and laminin.

424. The composition of claim 405, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a tumor vasculature associated antigen.

425. The composition of claim 424, wherein the tumor vasculature associated antigen is selected from the group consisting of endoglin, ELAM-1, VCAM-1, ICAM-1, ligand reactive with LAM-1, MHC class II antigens, aminophospholipids such as phosphatidylserine and phosphatidylethanolamine, VEGFR1 (Flt-1), VEGFR2 (KDR/Flk-1), and a complex of a growth factor and its receptor such as a complex of FGF and the FGFR or a complex of TGFβ and the TGFβR.

426. The composition of claim 424, wherein the antibody or antibody specific for a tumor vasculature associated antigen is selected from the group consisting of TEC-4 and TEC-11, 2C3 (ATCC PTA 1595), GV39 and GV97.

427. The composition of claim 405, further comprising a housing and instructions for use.

428. The composition of claim 427, wherein the instructions for use indicate that the antibody or antibody fragment is administered on a first day of a seven day cycle and the agent of Formula I is administered twice a day on day two through day seven.

429. The composition of claim 428, wherein the seven day cycle is repeated twice, thrice, or four times.

430. The composition of claim 428, wherein the seven day cycle is repeated for a month, two months, or three months.

431. The composition of claim 405, wherein the antibody or antibody fragment is conjugated to a toxin derived from plant, fungus, or bacteria.

432. The composition of claim 431, wherein the toxin is selected from the group consisting of A chain toxin, deglycosylated A chain toxin, ribosome inactivating protein, α-sarcin, aspergillin, restrictocin, ribonuclease, diptheria toxin and Pseudomonas exotoxin.

433. The composition of claim 405, wherein the antibody or antibody fragment is conjugated to a chemotherapeutic agent or a radioisotope.

434. The composition of claim 433, wherein the chemotherapeutic agent is selected from the group consisting of an anti-metabolite, an anthracycline, a vinca alkaloid, an antibiotic, an alkylating agent, and an epipodophyllotoxin.

435. The composition of claim 405, wherein the antibody or antibody fragment is selected from the group consisting of Avastin (bevacizumab), BEC2 (mitumomab), Bexxar (tositumomab), Campath (alemtuzumab), CeaVac, Herceptin (trastuzumab), IMC-C225 (centuximab), LymphoCide (epratuzumab), MDX-210, Mylotarg (gemtuzumab ozogamicin), Panorex (edrecolomab), Rituxan (rituximab), Theragyn (pemtumomab), Zamyl, and Zevalin (ibritumomab tituxetan).

436. The composition of claim 418, wherein the cancer antigen is selected from the group consisting of VEGF, Anti-idiotypic mAb (GD3 ganglioside mimic), CD20, CD52, Anti-idiotypic mAb (CEA mimic), ERBB2, EGFR, CD22, ERBB2 X CD65 (fcγRI), CD33, EpCam, and PEM.

437. A composition comprising

an effective amount of an agent of Formula I and a cancer antigen,

wherein the agent of Formula I is formulated for administration by injection or in an enterically coated form.

438. The composition of claim 437, wherein the effective amount is an amount to treat or prevent cancer.

439. The composition of claim 437, wherein the cancer antigen is a peptide antigen.

440. The composition of claim 437, wherein the cancer antigen is a lipid antigen.

441. The composition of claim 437, wherein the cancer antigen is selected from the group consisting of MART-1/Melan-A, gp100, adenosine deaminase-binding protein (ADAbp), FAP, cyclophilin b, colorectal associated antigen (CRC)--C017-1A/GA733, carcinoembryonic antigen (CEA), CAP-1, CAP-2, etv6, AML1, prostate specific antigen (PSA), PSA-1, PSA-2, PSA-3, prostate-specific

membrane antigen (PSMA), T-cell receptor/CD3-zeta chain, HER 2, CD33, EGF receptor, HLA markers such as HLA-DR, CD52, CD1, CEA, CD22, GD2 ganglioside, FLK2/FLT3, VEGF, VEGFR and CD20.

442. The composition of claim 437, wherein the cancer antigen is selected from the group consisting of MAGE-A1, MAGE-A2, MAGE-A3, MAGE-A4, MAGE-A5, MAGE-A6, MAGE-A7, MAGE-A8, MAGE-A9, MAGE-A10, MAGE-A11, MAGE-A12, MAGE-Xp2 (MAGE-B2), MAGE-Xp3 (MAGE-B3), MAGE-Xp4 (MAGE-B4), MAGE-C1, MAGE-C2, MAGE-C3, MAGE-C4, MAGE-C5).

443. The composition of claim 437, wherein the cancer antigen is selected from the group consisting of GAGE-1, GAGE-2, GAGE-3, GAGE-4, GAGE-5, GAGE-6, GAGE-7, GAGE-8, GAGE-9.

444. The composition of claim 437, wherein the cancer antigen is selected from the group consisting of BAGE, RAGE, LAGE-1, NAG, GnT-V, MUM-1, CDK4, tyrosinase, p53, MUC family, HER2/neu, p21ras, RCAS1, α-fetoprotein, E-cadherin, α-catenin, β-catenin, γ-catenin, p120ctn, $gp100^{Pmel117}$, PRAME, NY-ESO-1, cdc27, adenomatous polyposis coli protein (APC), fodrin, Connexin 37, Ig-idiotype, p15, gp75, GM2 ganglioside, GD2 ganglioside, human papilloma virus proteins, Smad family of tumor antigens, lmp-1, P1A, EBV-encoded nuclear antigen (EBNA)-1, brain glycogen phosphorylase, SSX-1, SSX-2 (HOM-MEL-40), SSX-1, SSX-4, SSX-5, SCP-1 and CT-7, and c-erbB-2.

445. The composition of claim 437, wherein the agent of Formula I is formulated for administration at a dose of greater than 10^{-8}M.

446. The composition of claim 418 or 437, wherein the cancer antigen is a gene or gene product thereof that has undergone chromosomal alteration.

447. The composition of claim 446, wherein the gene product is an RNA or protein gene product.

448. The composition of claim 446, wherein the gene or gene product thereof that has undergone chromosomal alteration is selected from the group consisting of gene or gene products associated with activation of quiescent genes, and gene or gene products associated with a novel fusion gene and protein.

449. The composition of claim 448, wherein the gene or gene products associated with activation of quiescent genes is selected from the group consisting of *BCL-1 and IgH; BCL-2 and IgH; BCL-6, TAL-1 and TCRδ or SIL* ; *c-MYC and IgH or IgL; MUN/IRF4 and IgH;* and *PAX-5 (BSAP)*

450. The composition of claim 448, wherein the gene or gene products associated with a novel fusion gene and protein is selected from the group consisting of *RARα, PML, PLZF, NPM or NuMA, BCR and ABL, MLL (HRX), E2A and PBX or HLF, NPM, ALK,* and *NPM, MLF-1.*

451. The composition of claim 418 or 437, wherein the cancer antigen is a tissue- or lineage-specific antigen.

452. The composition of claim 451, wherein the tissue- or lineage-specific antigen is a cell surface protein, epidermal growth factor receptor, cell-associated protein, or a secreted protein.

453. The composition of claim 452, wherein the cell surface protein is selected from the group consisting of CD20, CD22, CD52, CD33, CD10 (gp100), CD3/T-cell receptor (TCR), CD79/B-cell receptor (BCR), CD26, Human leukocyte antigen (HLA)-DR, HLA-DP, and HLA-DQ, RCAS1, and Prostate specific membrane antigen.

454. The composition of claim 452, wherein the epidermal growth factor receptor is selected from the group consisting of EGFR (HER1 or erbB1) and EGFRvIII, erbB2 (HER2 or HER2/neu), erbB3 (HER3), and erbB4 (HER4).

455. The composition of claim 452, wherein the cell-associated protein is selected from the group consisting of Tyrosinase, Melan-A/MART-1, tyrosinase related protein (TRP)-1/gp75 , Polymorphic epithelial mucin (PEM), and Human epithelial mucin (MUC1).

456. The composition of claim 452, wherein the secreted protein is selected from the group consisting of Monoclonal immunoglobulin, Immunoglobulin light chains, α-fetoprotein, Kallikreins 6 and 10, Gastrin-releasing peptide/bombesin, and Prostate specific antigen.

457. The composition of claim 418 or 437, wherein the cancer antigen is a cancer testis (CT) antigen.

458. The composition of claim 298, wherein the cancer testis (CT) antigen is selected from the group consisting of MAGE, MAGE-A1, -A3, -A6, -A12, MAGE-3, BAGE, GAGE, GAGE -1, -2, -3, -4, -5, -6, -7, and -8, HAGE, LAGE-1, NY-ESO-1, RAGE, RAGE-1, -2, -4, SSX, SSX-1, -2, -3, -4, -5, -6, -7, -8, -9, HOM-TES-14/SCP-1, HOM-TES-85, HOM-MEL-40, and PRAME.

459. The composition of claim 418 or 437, wherein the cancer antigen is a non-tissue or non-lineage specific antigen.

460. The composition of claim 459, wherein the non-tissue or non-lineage specific antigen is a carcinoembryonic antigen family member.

461. The composition of claim 460, wherein the carcinoembryonic antigen family member is selected from the group consisting of CD66a, CD66b, CD66c, CD66d and CD66e.

462. The composition of claim 418 or 437, wherein the cancer antigen is a viral protein.

463. The composition of claim 462, wherein the viral protein is selected from the group consisting of Human papilloma virus protein and EBV-encoded nuclear antigen (EBNA)-1.

464. The composition of claim 418 or 437, wherein the cancer antigen is an antigen that is mutated or aberrantly expressed in a cancer.

465. The composition of claim 464, wherein the antigen that is mutated or aberrantly expressed in a cancer is CDK4 or beta-catenin.

466. The composition of claim 418 or 437, wherein the cancer antigen is selected from the group consisting of VEGF, Anti-idiotypic mAb (GD3 ganglioside mimic), CD20, CD52, Anti-idiotypic mAb (CEA mimic), ERBB2, EGFR, CD22, ERBB2 X CD65 (fcγRI), CD33, EpCam, and PEM.

467. A composition comprising

an effective amount of an agent of Formula I and a microbial antigen,

wherein the agent of Formula I is formulated for administration by injection or in an enterically coated form.

468. The composition of claim 467, wherein the effective amount is an amount to treat or prevent an infectious disease.

469. The composition of claim 467, wherein the microbial antigen is a peptide antigen.

470. The composition of claim 467, wherein the microbial antigen is a lipid antigen.

471. The composition of claim 467, wherein the microbial antigen is selected from the group consisting of a bacterial antigen, a mycobacterial antigen, a viral antigen, a fungal antigen, and a parasitic antigen.

472. The composition of claim 471, wherein the bacterial antigen is derived from a bacterial species selected from the group consisting of E. coli, Staphylococcal, Streptococcal, Pseudomonas, Clostridium difficile, Legionella, Pneumococcus, Haemophilus, Klebsiella, Enterobacter, Citrobacter, Neisseria, Shigella, Salmonella, Listeria, Pasteurella, Streptobacillus, Spirillum, Treponema, Actinomyces, Borrelia, Corynebacterium, Nocardia, Gardnerella, Campylobacter, Spirochaeta, Proteus, Bacteriodes, H. pylori, and anthrax.

473. The composition of claim 471, wherein the viral antigen is derived from a viral species selected from the group consisting of HIV, Herpes simplex virus 1, Herpes simplex virus 2, cytomegalovirus, hepatitis A virus, hepatitis B virus, hepatitis C virus, human papilloma virus, Epstein Barr virus, rotavirus, adenovirus, influenza A virus, respiratory syncytial virus, varicella-zoster virus, small pox, monkey pox, and SARS.

474. The composition of claim 471, wherein the fungal antigen is derived from a fungal species that causes an infection selected from the group consisting of candidiasis, ringworm, histoplasmosis, blastomycosis, paracoccidioidomycosis, crytococcosis, aspergillosis, chromomycosis, mycetoma infections, pseudallescheriasis, and tinea versicolor infection.

475. The composition of claim 471, wherein the parasitic antigen is derived from a parasite species selected from the group consisting of amebiasis, Trypanosoma cruzi, Fascioliasis, Leishmaniasis, Plasmodium, Onchocerciasis, Paragonimiasis, Trypanosoma brucei, Pneumocystis, Trichomonas vaginalis, Taenia, Hymenolepsis, Echinococcus, Schistosomiasis, neurocysticercosis, Necator americanus, and Trichuris trichuria.

476. The composition of claim 471, wherein the mycobacterial antigen is derived from a mycobacterial species selected from the group consisting of M. tuberculosis and M. leprae.

477. The composition of claim 405, 437 or 467, wherein the agent of Formula I is an agent of Formula II.

478. The composition of claim 405, 437 or 467, wherein the agent of Formula I is an agent of Formula III.

479. The composition of claim 405, 437 or 467, wherein the agent of Formula I is Ile-boroPro.

480. The composition of claim 405, 437 or 467, wherein injection is subcutaneous injection.

481. The composition of claim 405, 437 or 467, wherein injection is intravenous injection, intramuscular injection, intraperitoneal injection, intra-tumor injection.

482. The composition of claim 405, 437 or 467, wherein the enterically coated form is a pill, a capsule or a tablet.

483. The composition of claim 405, 437 or 467, wherein the effective amount is about 0.005 mg/kg to less than 1.0 mg/kg body weight per day.

484. The composition of claim 405, 437 or 467, wherein the agent of Formula I is at least 96% pure L-isomer.